

## Effective Treatment of Acute Otitis Externa: a Comparison of Steroid Antibiotic Versus 10% Ichthammol Glycerine Pack

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**Abstract** To compare the efficacy of treatment between steroid–antibiotic and 10% Ichthammol glycerine packs (IG packs) in acute otitis externa. A prospective, randomized clinical trial between steroid–antibiotic and 10% IG pack which was performed in department of ENT-HNS, Kathmandu University Hospital, Dhulikhel from July 2009 to December 2009 on 82 patients. Pain was assessed by Numerical Rating Scale (NRS) and edema was assessed by dividing the external auditory canal in four quadrant giving score of 25% for each on the day of presentation and subsequent visits till tragal tenderness and edema subsided. Age group among studied patients ranged from 10 to 60 years, with mean of 23.5 years. Out of which 42 (51.2%) were females and 40 (48.8%) were males. Average number of visits in 10% IG pack group ( $n = 41$ ) was 5.4 days (2–5 visits) while in steroid–antibiotic group ( $n = 41$ ) it was 3.5 days (2–5 visits). There was statistically significant decrease in the number of visits in steroid group ( $P < 0.05$ ). Similarly, decrease in pain score in second visit was statistically significant ( $P = 0.02$ ) in steroid–antibiotic group as compared to 10% IG pack, while the edema score in second visit while comparing steroid–antibiotic group with 10% IG pack was statistically not significant ( $P = 0.07$ ), whereas it was statistically highly significant on fourth visit ( $P = 0.001$ ). Since the control of pain and edema is more and hence the number of visits is significantly less in steroid–antibiotic packing group, so it is worthwhile to use steroid–antibiotic pack for effective treatment of acute otitis externa.

**Keywords** Acute otitis externa · Numeric rating scale · Steroid–antibiotic pack · 10% Ichthammol glycerine pack

### Introduction

Otitis externa is a generalized condition of the skin of the external auditory canal that is characterized by general edema and erythema. It can present as diffuse or localized form of inflammation of external ear canal. It is the very common condition which is encountered in day to day outpatient services. Any condition or situation that disturbs the lipid/acid balance of the ear will predispose an individual to Otitis externa [1]. Edema occurring due to inflammation distracts the periosteal lining of bony canal causing extreme amount of pain [2]. So treatment includes not only antibiotics and analgesics systemically but also aural packing. It acts by its chemical ingredients and also mechanically by splinting action pressing the soft tissues towards the non-distended position. Traditionally these packs are impregnated with 10% Ichthammol glycerine. Ichthammol has antiseptic action while glycerine has its hygroscopic nature. The combination solution has a specific antistaphylococcal action [3, 4]. Steroid–antibiotic cream can serve both functions. Steroid reduces edema by its action over capillary wall tone and antibiotic controls infection. Different studies about comparison of different antibiotics and steroid combinations have been done. [5–10] Topical antibiotic–steroid combination therapy is superior to steroid therapy alone for symptomatic control of otitis externa. [11, 12] We performed this study to observe the effectiveness of treatment for relieving pain and edema by comparing steroid–antibiotic with 10% Ichthammol glycerine.

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## Materials and Methods

Patients of all age groups and both gender presenting in OPD of ENT-HNS Department of Kathmandu University Hospital, Dhulikhel from July 2009 to December 2009 and diagnosed to have acute otitis externa were included. The total number of patients with acute otitis externa needing aural packing was 93. Out of them eight lost follow up and three had concomitant chronic suppurative otitis media tubo-tympanic type. These cases were excluded from the study. Hence, 82 patients were included in the study. Patients needing aural packing were randomized. And alternatively 10% IG Pack and steroid–antibiotic pack were kept. For steroid–antibiotic combination, we used the BETNOVATE-N, a combination of betamethasone valerate and neomycin. Before packing was carried out, pain was assessed. Since, all our patients were above 12 years of age, we used a ten point Numerical Rating Scale (NRS) and the score was given by the patient. Similarly for scoring of edema we divided the external auditory canal in four parts with 25% for each and scoring was performed as per the percentage of the involvement of canal by the same ENT surgeon. Score of pain and edema on first visit was recorded. To comply with therapeutic guidelines and to offer the patient a rescue medication we distributed the same systemic antibiotic (cloxacillin) and analgesic (paracetamol). Patients were called after 48 h for reassessment. On subsequent visits, they were called in the early morning without taking morning dose of analgesic so that the scoring performed at that time was not influenced by analgesics. If tragal tenderness and canal swelling was present repacking was done and asked for follow up again after another 48 h. Assessment and repacking was done every 48 h till tragal tenderness disappeared and edema subsided completely. Statistical analysis was done using “Z” test of mean to compare average number of score and visits in two different groups.

## Results

The total number of patients included in the study was 82. Among them 40 (48.8%) were male and 42 (51.2%) were female (Table 1). The age group ranged from 10 to 60 years (mean = 23.5) as shown in Table 2. In 41 (50%) patients 10% IG packing was performed whereas in another 41 (50%) patients steroid–antibiotic pack was kept. The

**Table 2** Showing age distribution ( $n = 82$ )

| Age group   | Total number of patients |
|-------------|--------------------------|
| 10–20 Years | 35 (42.7%)               |
| 21–30 Years | 28 (34.1%)               |
| 31–40 Years | 12 (14.6%)               |
| 41–50 Years | 6 (7.3%)                 |
| 51–60 Years | 1 (1.2%)                 |

average duration of pain among included patient was 2.55 days (1–7 days) on presentation. Ten (12.2%) patients had history of fever and malaise whereas another 10 (12.2%) patients had history of pain in movement of jaw. Regarding the OPD follow up, in 10% IG pack, 1 (2.4%) patient had maximum number of seven visits whereas in steroid–antibiotic group, maximum number of visit was five done by 8 (19%) patients (Table 3). Regarding the status of pain there was statistically significant decrease in pain in steroid–antibiotic group as compared to 10% Ichthammol glycerine group on second visit ( $P = 0.02$ ). Regarding status of edema, there was statistically significant decrease in edema on fourth visit in steroid–antibiotic group as compared to 10% Ichthammol glycerine group ( $P = 0.007$ ). The edema was completely subsided on fifth visit in steroid–antibiotic group whereas it was on sixth visit in 10% IG Pack (Table 4). So, the average number of visits in 10% IG Pack was 5.4 days whereas in steroid–antibiotic pack it was 3.5 days and this difference was statistically significant ( $P < 0.05$ ). Similarly in edema control, there was statistically significant difference between steroid–antibiotic as compared to 10% ichthammol glycerin ( $P < 0.05$ ).

## Discussion

Acute otitis externa (AOE) is a frequent disease mostly caused by bacteria and triggered by moisture [13]. The dominating pathogens are *Staphylococcus aureus* and *Pseudomonas aeruginosa*, in about 10% of cases fungi mainly (*Aspergillus* sp.) are detected [14]. In otitis externa, the main aim of treatment is to control edema and pain. In this study on the treatment of AOE, we intended to compare the effectiveness of steroid–antibiotic versus 10% Ichthammol glycerin pack. The use of an ointment instead of drops in the treatment of otitis externa can be seen from two points of view. On the one hand, the occlusive effect of an ointment may raise the humidity in the affected ear [15]. On the other hand, fewer hypersensitivity reactions are to be expected because no preservatives, which may cause allergic reactions, are required for water-free ointments, whereas eardrops are often preserved. Drugs present in ear

**Table 1** Showing sex distribution of patients ( $n = 82$ )

| Male       | Female     |
|------------|------------|
| 40 (48.8%) | 42 (51.2%) |

**Table 3** Showing total number of visits till complete pain relief between two groups ( $n = 82$ )

| Number of visits till complete pain relief         | 2        | 3        | 4          | 5          | 6          | 7        |
|--|----------|----------|------------|------------|------------|----------|
| 10% IG pack (no. of patients) $n = 41$             | 1 (2.4%) | 3 (7.3%) | 7 (17.1%)  | 14 (34.1%) | 15 (36.6%) | 1 (2.4%) |
| Steroid-antibiotic pack (no. of patients) $n = 41$ | 2 (4.8%) | 16 (39%) | 15 (36.6%) | 8 (19.5%)  | 0 (0%)     | 0 (0%)   |
| P value  | 0.79     | 0.02     | 0.001      | 0.0001     | 0.0001     | 0.0001   |

**Table 4** showing the total number of visits till complete subsidence of edema ( $n = 82$ )

| Number of visits till complete subsidence of edema | 2         | 3          | 4          | 5          | 6        |
|--|-----------|------------|------------|------------|----------|
| 10%IG pack (no. of patients) $n = 41$              | 5 (12.2%) | 8 (19.5%)  | 10 (24.4%) | 17 (41.5%) | 1 (2.4%) |
| Steroid-antibiotic pack (no. of patients) $n = 41$ | 2 (4.8%)  | 17 (41.5%) | 16 (39%)   | 6 (14.6%)  | 0 (0%)   |
| P value  | 0.21      | 0.078      | 0.25       | 0.007      | 0.0001   |

drops are potentially ototoxic, if used for a prolonged period in perforated tympanic membrane [16]. So, aural packing impregnated with topical preparation is used to decrease pain and edema. Topical medications will not be able to penetrate an edematous canal wall, a problem that can be overcome by the insertion of an ear wick [16]. Hence insertion of wick is a better topical therapy of otitis externa than instilling ear drops [17]. As both Gram positive and Gram negative bacteria cause infection of the external ear, so broad spectrum antibiotics are required for the treatment. Application of topical preparation is generally the treatment of choice because high concentration of active agents can be delivered to the site of infection with minimal side effects [13, 14]. Thus, organisms listed as “resistant” to a particular antibiotic will likely be susceptible to the antibiotic when it is given topically [16]. Many bacterial (including pseudomonas) and fungal species are killed by the acidified environment of the ear canal. Thus, topical medications with an acidic pH have been a mainstay of treatment for otitis externa [16]. Studies using drop also showed significant improvement with steroid and antibiotic combination when compared with only antibiotic drop. There are few studies which compared the single topical agent with topical and oral antibiotic. Whereas we performed the studies using same antibiotics (cloxacillin) and analgesics (paracetamol) in all included patients to avoid bias. Masood et al. [18] in their randomized control trial used steroid pack and found statistically significant improvement in pain parameters when compared with 10% IG pack. Similar prospective study performed by Hornigold et al. [19] using topical steroid ear drops failed to show any difference. Study performed by Bhatt et al. [20] showed statistically significant decrease in pain and number of visits in steroid-antibiotic group as compared to 10% ichthammol glycerine pack. In our study, there was complete reduction in pain on the fifth visit in the steroid-antibiotic group whereas in the 10% IG pack group it was only on the seventh visit. We also compared the edema

reduction between steroid-antibiotic with 10% Ichthammol glycerin. We found that there was complete reduction in edema on the fifth visit in the steroid-antibiotic group whereas it was on sixth visit in 10% Ichthammol glycerine group, showing less number of visits and thus early control of pain and edema in steroid-antibiotic group. So in our study, there was statistically significant reduction in pain, edema and reduction in number of visits in steroid-antibiotic group as compared to 10% ichthammol glycerine group which is similar to study performed by Masood et al. and Bhatta et al. The sample size is also greater than the study performed by Massod et al. and Hemigold et al., but it is comparable to study performed by Bhatt et al. In our study we found that the frequency of otitis externa is more common in young adults like that of study performed by Bhatt et al. but differs with Neher et al. [21]. It was more common in female which differed from study performed by Bhatt et al., may be because in the village, women clean their external auditory canal with feather of birds or hair pin. We did not find any side effects so far in the both groups.

## Conclusion

Since the control of pain and edema is more and hence the number of visits is significantly less in steroid-antibiotic packing group, so it is worthwhile to use steroid-antibiotic pack for effective treatment of acute otitis externa.

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